



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
66/548,229	11/02/89	REDDY	

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EXAMINER	
PATENT	
ART. UNIT	PAPER NUMBER
	22

DATE MAILED: 11/16/87

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on July 27, 1987 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☒ Examiner's Interview Summary Form.

Part II SUMMARY OF ACTION

1. ☒ Claims 5, 7, 9-15, 17-31, 33, 37, 38 and 40-46 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 5, 7, 9-15, 17-31, 33, 37, 38 and 40-46 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Claims 5, 7, 9, 10, 12-15, 17, 19, 20, 33 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specification on pages 1-3 and 17-22. See MPEP 706.03(n) and 706.03(z).

This rejection is repeated for essentially the same reasons as set forth in the previous office action. Applicants argue that due to the pioneering nature of their invention, the scope of their claims should encompass any eukaryotic cell and therefore should not be limited to mammalian cells. However, it is maintained that applicants' arguments regarding the proper processing and assembly of the alpha and beta subunit into a biologically functional dimeric hormone in the transformed host supports the examiner's position in this rejection. Therefore, the host appears to be critical in the proper processing of the hormones and this rejection is maintained.

Claims 5, 10-15, 17-21, 29, 37, 41 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 17 and 19 are indefinite in failing to provide proper antecedent basis for "said heterodimeric hormone". It should be noted that claims 13 and 14

ment to claim 12. Claim 5 is incomplete in failing to set forth that the beta subunit is encoded. It would appear that this limitation is critical to obtain a biologically active hCG or LH. Claim 20 is redundant in reciting that "said alpha subunit being encoded by a first expression vector" because claim 5 already contains this limitation. It appears that claims 9 and 12 are comparable in scope and therefore appear to be redundant.

Claim 29 contains an inadvertent error by reciting "pRF375" rather than "pRF398" as set forth in original claim 29. As claim 29 is presently recited, it is the same as claim 28.

Claim 41 is indefinite in depending from cancelled claim 34. It appears that changing the dependency was an oversight.

Claims 11 and 45 are identical and therefore redundant.

It should be noted that the amendment to claim 6 requested in the amendment of August 14, 1987 was not made because claim 6 has been cancelled.

Claims 5, 7, 9-15, 17-31, 33 and 37-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-22, 24-26, 28-32, 36, 37, 40-61,

no. 016,673, a CIP of 811,959, now abandoned which is a continuation of 548,211, now abandoned. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to cells containing expression vectors encoding for subunits of a heteropolymeric protein, vectors coding for heteropolymeric proteins and methods for producing heteropolymeric proteins. In regard to claims 40-61, 63-66, 68-70 and 72-78, it would be obvious to utilize the DNA coding for human fertility hormones (heteropolymeric proteins) contained in the expression vectors of the present case as probes to isolate the DNA encoding for the ungulate fertility hormones. The ungulate DNA could then be utilized to construct vectors and transformed hosts to utilize the methods of serial no. 016,673.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 5, 7, 9-13, 17, 18, 21-25, 33, 37, 38 and 40-45 are rejected under 35 U.S.C. 103 as being unpatentable over Fiddes et al (1981), Fiddes et al (1980) and Pierce et al in view of Moriarty et al and Rice et al.

This rejection is maintained for essentially the same reasons as set forth in the previous office action. Applicants argue that the combination of the prior art does not suggest production of a human fertility hormone in one cell transformed with DNA encoding both the alpha

Moriarty et al and Rice et al do not teach the assembly of dimeric proteins cloned in cells which do not normally produce these proteins.

Applicants' arguments have been considered; however applicants' claims are not limited to the host cells which are responsible for assembly of the alpha and beta subunits of hCG or LH. Although claims 11 and 45 are limited to mammalian cells, claim 18 is limited to monkey cells and claim 21 is limited to mouse cells, it is unclear from the specification that transformation of either mouse or monkey cells results in production of biologically active hCG or LH. Further, claims 22-31 and 40 do not require a particular host cell limitation, but are drawn to expression vectors encoding alpha and beta subunits of a human fertility hormone, hCG and LH.

Applicants argue that Rice et al involve the production of a dimer where the heavy chain is already produced by the cell prior to transformation with DNA encoding the light chain and that their invention encompasses a cell in which both chains of a dimeric protein are encoded by vectors. However, claim 5 does not require the limitation that both chains are encoded by vectors. Claim 5 only requires the alpha subunit to be encoded by a vector.

Claims 14, 19, 26, 27 and 30 are rejected under 35

al(1981), Fiddes et al(1980) and Pierce et al in view of Moriarty et al and Rice et al and further in view of Reddy et al and Hamer et al.

This rejection is repeated for essentially the same reasons as set forth in the previous office action and for the reasons set forth above.

Claims 15, 20, 28, 29 and 31 are rejected under 35 U.S.C. 103 as being unpatentable over Fiddes et al(1981), Fiddes et al(1980) and Pierce et al in view of Moriarty et al and Rice et al and further in view of Reddy et al, Hamer et al and Sarver et al.

This rejection is repeated for essentially the same reasons as set forth in the previous office action and for the reasons set forth above.

Claim 46 is rejected under 35 U.S.C. 103 as being unpatentable over Fiddes et al(1980) in view of Fiddes et al(1981).

Fiddes et al(1980) teach the cDNA sequence for the beta subunit of hCG and that the beta subunits of hCG and LH have 82% homology. Further, this reference teaches that LH is synthesized in the anterior pituitary. Fiddes et al(1981) teach a method of isolation of chromosomal gene sequences encoding the alpha subunit of the glycoprotein hormones utilizing hybridization probes. In the absence of unexpected results, it would be

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LH utilizing the method of Fiddes et al(1981) utilizing the beta subunit of hCG as taught by Fiddes et al (1980) as a probe to isolate a cDNA encoding for the beta subunit of LH as suggested by Fiddes et al(1980) teaching an 82% homology between the beta subunit of hCG and LH.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP 706.07(a).

Applicant is reminded of the extension of time policy set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Jayme A. Huleatt at telephone number 703-557-1748.

JAH

HULEATT:pc

10/29/87

[Signature]
THOMAS G. WISEMAN
SUPERVISORY PATENT EXAMINER
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